DEC 2 1 2012

Southern Spine LLC
Traditional 510(k) - Southern Spine - StabiLink™ MIS Spinal Fixation System

510(k) SUMMARY

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements under 21 CFR 807.92.

Submitted By: Southern Spine LLC
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Contact Person: Julie Stephens, President/Consultant
Regulatory Resources Group, Inc.

Date Submitted: November 29, 2012

Device Name and Classification:

Trade/Proprietary Name:	StabiLink™ MIS Spinal Fixation System
Common Name:	Appliance, Fixation, Spinal Interlaminal
Classification Name:	Spinal interlaminal fixation orthosis
Product Code:	KWP

Legally Marketed Predicate Device:

Lanx, Inc. - Lanx Spinal Fixation System (Includes Lanx Aspen and LPlate Systems) – 510(k) # K071877 (Initial Aspen); K083581; K090252; K100935 (Initial LPlate); K103091; K121940

Medtronic Sofamor Danek, Inc. - CD HORIZON® Spinous Process Plate (Also called Spire™) - 510(k) # K032037

Device Description:

The StabiLink™ MIS Spinal Fixation System is a posterior, non-pedicle supplemental fixation device, intended for use in the non-cervical spine (T1-S1). It is intended for plate fixation/attachment to spinous processes for the purpose of achieving supplemental fusion. The system is implanted via a posterior approach to the spine. The StabiLink™ MIS Spinal Fixation System includes various sizes of Titanium plate constructs. There is instrumentation for implantation and a sterilization tray for steam sterilization. The implants are non-sterile and single use. The instrumentation is non-sterile and reusable.

Indications for Use:

The StabiLink™ MIS Spinal Fixation System is a posterior, non-pedicle supplemental fixation device, intended for use at a single level in the non-cervical spine (T1-S1). It is intended for plate fixation/ attachment to spinous processes for the purpose of achieving supplemental fusion in the following conditions: degenerative disc disease (DDD) (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radio-graphic studies); spondylolisthesis; trauma (i.e., fracture or dislocation); tumor. It is not intended for stand-alone use.

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Similarities and Differences to the Predicate Devices:

Similarities

The StabiLink™ MIS Spinal Fixation System like the predicate devices uses a two piece construct that fits over the spinous process. All three devices use a sliding type mechanism between the two pieces which are then compressed into the bone and the construct is locked with a set screw. The same materials, same performance standards, and the same indications for use are used in the StabiLink and the predicate devices.

Differences

There are slight differences in the StabiLink when compared against the predicates. The StabiLink and the Spire both have four fixation spikes on each wing (two wings on each side piece of the plate construct) while the Lanx plates have three spikes on each wing. The StabiLink and Lanx have conical shaped fixation spikes while the Spire has pyramid shaped fixation spikes.

Summary of Testing:

The StabiLink MIS Spinal Fixation System was tested to the ASTM F1717 standard as recognized by FDA as appropriate for characterization of posterior non-cervical non-pedicle systems. Testing included static and dynamic axial compression bending, and static and dynamic torsion. These tests were identified in "FDA Guidance for Industry and Staff - Spinal System 510(k)s", Dated May 3, 2004. Further guidance and discussion with FDA personnel led to additional requested testing for static tension testing using foam blocks, and dissociation testing using a modification of ASTM F1798 which tests the resistance to lateral loading of the component interconnection mechanisms. The ASTM F1717 tests were completed as direct comparison tests with the predicate devices. The results from the direct comparison demonstrate substantial equivalence for the static and dynamic axial compression bending, static and dynamic torsion, and the static tension testing. Dissociation testing was also completed.

Substantial Equivalence Conclusions:

The StabiLink MIS Spinal Fixation System has the same intended use and indications for use, and the same or very similar technological characteristics and principles of operation as the predicate systems. The minor differences do not raise any issues of safety or effectiveness. Testing results support the determination of substantial equivalence with the results demonstrating that the StabiLink has equivalent or in some cases better results than the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Southern Spine, LLC
% Ms. Julie Stephens
President/Consultant
111 Laurel Ridge Drive
Alpharetta, Georgia 30004

December 20, 2012

Re: K123093
Trade/Device Name: Southern Spine - StabiLink™ MIS Spinal Fixation System
Regulation Number: 21 CFR 888.3050
Regulation Name: Spinal interlaminal fixation orthosis
Regulatory Class: Class II
Product Code: KWP
Dated: November 29, 2012
Received: November 30, 2012

Dear Ms. Stephens:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Peter D. Rumm -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K123093

Indications for Use

510(k) Number (if known):

Device Name: Southern Spine - StabiLink™ MIS Spinal Fixation System

Indications for Use:

The StabiLink™ MIS Spinal Fixation System is a posterior, non-pedicle supplemental fixation device, intended for use at a single level in the non-cervical spine (T1-S1). It is intended for plate fixation/ attachment to spinous processes for the purpose of achieving supplemental fusion in the following conditions: degenerative disc disease (DDD) (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radio-graphic studies); spondylolisthesis; trauma (i.e., fracture or dislocation); tumor. It is not intended for stand-alone use.

Prescription Use ___X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Ronald P. Jean -S

(Division Sign-Off)
Division of Orthopedic Devices
510(k) Number: K123093